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10/612,171	07/01/2003	Carol A. Tosaya	D-02017A	5208

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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/612,171	TOSAYA ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79,81-86 and 88-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44,47-60,62-79,81-86 and 88-96* is/are rejected.

7)☒ Claim(s) *30,32,34,44-46,61,72,77,78 and 82* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Further search has been performed and newly discovered prior art has been applied to certain claims which were previously objected to but would be allowable if re-written in independent form. See the rejections below.

Claim Objections

Claims 30, 32, 34, 44, 72, 77, 78 and 82 are objected to because of the following informalities:

Claim 30 states the use of at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content is utilized. However, independent claim 1 states that a drug, medicament or controlled dietary content is not required. It is unclear as to whether a "drug, medicament or controlled dietary content" are to be treated differently from a "vitamin, mineral or controlled dietary matter" with respect to claim 30. The Applicant is requested to inspect other claims for similar incidences.

Claim 32 states that the enablement, enhancement, initiation, extension or acceleration is at least one of: (1) cause by interaction of acoustic or vibratory energy with a drug or (2) causing the acoustic or vibratory energy to prepare the anatomy for simultaneous exposure to a drug. This claim ultimately depends from claim 1, which

states that the drug is not necessary. However, the limitations of claim 32 positively require a drug.

Claim 34 states, "either unaided or in aided form, wherein said aid comprises one of:" Therefore, options (a), (b), (c), and (d) are irrelevant since the one drug, medicament, vitamin, mineral or ingested dietary content reaches a brain or neurological region by passing through the BBB unaided.

Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 1 and 44 provide for acoustic or vibratory exposure to allow therapy without requiring a drug.

The Examiner believes claim 72 should read, "The system of claim 1, wherein -- at least one of--:"

Claim 77 states, "wherein said at least one acoustic emitter is inside ... and said acoustic or vibratory energy emanates..." It is unclear as to whether an acoustic emitter is being claimed as opposed to "at least one acoustic or vibratory emitter", which is the claim language of independent claim 1.

Claim 82 depends from cancelled claim 80.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 67 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is directed to the removal of a nodule from the body by natural body processes.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 78, 88-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 states at line 3, "is diagnosed to *possibly, likely or certainly be one of more of...*" It is recommended this language be changed to, for example, -- is at least one of: --

Claim 78 does not positively claim beam-forming or beam-steering. A claim must distinctly point out what is patentable matter.

Claim 88 provides for an "optional drug, medicament or controlled dietary content..."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 11-16, 20-27, 30-32, 37-38, 44, 50-53, 56, 58, 60, 66, 71-73, 76, 78-79, 84, 86, 88-93 and 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bystritsky (US Patent No. 7,283,861). Bystritsky discloses a method for modifying electrical currents in brain circuits through the simultaneous use of focused ultrasound pulse (FUP) and existing brain imaging systems. The methods are used for research, treatment and diagnosis of neurological disorders whose biological mechanisms include brain circuits (*see* Abstract). Among other disorders this can be used for are Parkinsonian Disease, Huntington Chorea, La Touretts and tick syndromes (column 1, lines 25-45). The FUP can be focused to any location(s) in the brain and can account for bone density and structure of the skill and brain (column 4, lines 25-34). Repeated use of the methods disclosed by Bystritsky can cause long-term or permanent changes to the circuits (column 4, lines 45-59). This can be used to aid in the recovery, growth, regrowth, new growth or improved physical, biological and cognitive functionality of brain-related or neurological-related cells, or functional pathways negatively impacted or stressed by deposits, nodules or bodies. The methods may be used without additional agents, but may also be used concurrently with pharmaceutical agents (column 5, lines 21-32). It would have been obvious to one of skill in the art to use these methods on pathways that were adversely effected by

protein formation due to neurological disorders because the methods are specifically cited as a treatment for such diseases (i.e., Parkinsonian Disease, Huntington Chorea, etc.).

Regarding claims 24-26, these claims are method steps claim and do not limit the structure from which these claims ultimately dependent.

Regarding claim 31, the fact that acoustic or vibratory therapy exposure effects the action of the drug is not a structural limitation, but rather is a property based on the drug, medicament, vitamin, etc., that is given to the patient. Bystritsky is capable of enhancing the effects of certain drug, medicament, vitamin, etc., that would be given to the patient if the drugs are effected by ultrasound.

Regarding claim 60, if a patient is bald and the procedure of Bytritsky is performed, a patient with reduced hair quantity will have the device coupled.

Regarding claims 1, 30-43, 49 and 81, the system is claimed to function without the use of a drug, medicament, or controlled dietary content to proceed at a useful pace or to a useful extent. Therefore, the use of a drug, medicament, or controlled dietary content is optional. Since this is not necessary for the system, Bystritsky's methods and system cover these optional limitations.

Regarding claims 88-90 and 92, section (a) is the only portion of the claim that recites positive claim limitations. Section (b) is optional. The two "wherein" clauses following section (b) are intended use limitations. Therefore, the portion of claim 88 that bears patentable weight is limited to section (a), which Bystritsky reads on.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7-10, 17-19, 27-29, 30, 33-36, 39-43, 47-49, 57, 59, 62-70, 73-74, 77, 79, 81-83, 85-86, 88-90 and 94-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent No. 7,286,879) in view of Shalev et al. (US Patent Pub. No 2003/0176892). Wallace discloses a method or treating a neurological disorder in a patient. The method comprises introducing a stimulation lead within a patient's head, advancing the stimulation lead within an intracranial vascular body, placing the stimulation lead adjacent the fastigium nucleus of the patient's brain and stimulating the fastigium nucleus with the stimulation lead to treat the neurological disorder (*see* Abstract). Wallace states that this method can also be used to treat Alzheimer's patients by increasing the blood flow within the brain in order to help metabolize amyloid plaque (column 7, lines 27-29). However, Wallace uses electrical stimulation. In a similar field of endeavor, Shalev teaches a method and apparatus for stimulating the sphenopalatine ganglion to modify properties of the blood-brain barrier (BBB) and cerebral blood flow (paragraphs 36-41). Also provided at paragraph 43, Shalev states that the invention provides improved methods for treating neurological diseases (for example, Alzheimer's disease). Methods of stimulation are described as

electrical, however, mechanical vibration and ultrasonic transmission are both contemplated (paragraph 68). A temperature transducer is used to monitor the effect of the stimulation applied (paragraph 156).

Regarding claims 40 and 41, these claims are purely functional and do not provide patentable limitations for the system.

Regarding claims 35-36, 62-69, 81-83 and 85 are all intended use claims. These claims do not have patentable weight with regard to the system. Wallace and Shalev's methods and system cover these limitations.

Regarding claims 1, 30-43, 49 and 81, the system is claimed to function without the use of a drug, medicament, or controlled dietary content to proceed at a useful pace or to a useful extent. Therefore, the use of a drug, medicament, or controlled dietary content is optional. Since this is not necessary for the system, Wallace and Shalev's methods and system cover these optional limitations.

Regarding claims 88-90, section (a) is the only portion of the claim that recites positive claim limitations. Section (b) is optional. The two "wherein" clauses following section (b) are intended use limitations. Therefore, the portion of claim 88 that bears patentable weight is limited to section (a), which Wallace and Shalev's reads on.

Allowable Subject Matter

Claims 45, 46 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

JMK